Mission Statement

TRACE Analytical Laboratories, Inc. believes that providing accurate, timely and cost effective analytical data is the most important service that we as an organization can provide our clients. Working in partnerships, TRACE Analytical Laboratories, Inc. strives to serve our clients to the best of our abilities and provide a healthy, safe and productive work environment for our team members.

To that end, it shall be the purpose of TRACE Analytical Laboratories to implement internal programs, procedures, and policies that strengthen, augment and develop a sound environmental laboratory and meet the requirements outlined in the TNI Standard, the ISO/IEC 17025:2005 International Standard, the Department of Defense Quality Systems Manual, and guidelines developed by both regulatory agencies and private industries.

Disclaimer

The mention of trade names, commercial products or suppliers in this manual does not constitute any endorsement or recommendation for use by TRACE Analytical Laboratories, Inc.

Administrative Approval

TRACE ANALYTICAL LABORATORIES, INC.

Laboratory Operations and Quality Assurance Manual

Effective Date: 5-28-14

Concurrences and Approvals:

Name: Gina Roe
Title: Laboratory Manager
Signature:

Name: Alyson Yagiela
Title: QA/QC Manager
Signature:

Statement of Qualifications

OVERVIEW

TRACE Analytical Laboratories, Inc. (Trace) was founded in 1989. TRACE is a Veteran Owned Small Business full service environmental laboratory, providing a complete range of environmental analyses and sampling services for our clients. These services include organic and inorganic analyses of water, soil, air, and hazardous waste. All of our routine services conform to strict methodologies. These methods come from sources such as the US EPA, ASTM, AOAC, NIOSH, and Standard Methods.

TRACE has state-of-the-art analytical instrumentation using proven technology. Part of the Quality Assurance (QA) Program is obtaining, maintaining, and calibrating equipment and instrumentation that is required to accurately and efficiently carry out analysis of samples as prescribed in analytical test methods. TRACE purchases or prepares appropriate reagents and standards for analyses. Whenever possible these reagents and standards will be American Chemical Society (ACS) grade, spectroquality, or traceable to NIST standards. TRACE collects and receives samples under strict chain-of-custody procedures and adheres to proper sample collection and preservation techniques. The main goal of this QA Program is to provide our clients with the highest quality analytical results.

TRACE has substantial experience with servicing the analytical needs of clients in private industry, environmental consulting, federal agencies, and both state and local governmental units and is an entity that can be held legally responsible. Our laboratory continually supports regulatory programs like CERCLA/SARA, RCRA, Clean Air Act, Safe Drinking Water Act, NPDES and the Clean Water Act. TRACE is accredited in accordance with the National Environmental Laboratory Accreditation Program (NELAP)/TNI (The NELAC Institute), the Department of Defense Environmental Laboratory Accreditation Program (DoD-ELAP), and ISO/IEC 17025:2005. TRACE is also a Contract Laboratory for the Michigan Department of Environmental Quality and is certified by the State of Michigan for Drinking Water analysis.

TRACE's Project Managers work closely with their clients and laboratory personnel to ensure all details and project specifications are accurately performed. The Project Managers can assist in project planning, including the preparation of Quality Assurance Project Plans (QAPPs). Working with clients at the onset of a project assures the results are more conclusive and cost-effective.

TRACE is comprised of experienced professionals with degrees in chemistry, biology, and environmental science. Our team has specialized training in laboratory operations and experience in the industrial workplace. Their expertise guarantees our clients the range and depth of scientific disciplines, technical specialties, practical experience, and analytical services needed to meet the objectives of today's complex industrial and environmental demands.

Professional resumes for TRACE's key personnel are included in Appendix I.

Laboratory Identification

EPA Laboratory ID:	MI00106
DoD-ELAP Accreditation Number:	1031
New Jersey NELAP Certification ID Number:	MI008
State Of Michigan Laboratory ID:	8001

Please contact the QA/QC Manager at Trace for current versions of certifications.

How to Contact Trace

Mailing Address:

TRACE Analytical Laboratories, Inc.
2241 Black Creek Road
Muskegon, MI 49444-2673

When sending requests for quotation through regular mail, please add 'Quotation Request' to the address listed above.

Telephone:	(231) 773-5998
Toll Free:	(800) 733-5998
Fax:	(231) 773-6537
Web Site:	www.trace-labs.com
General E-mail Delivery:	info@trace-labs.com

SECTION 1: Introduction

Purpose:

The purpose of this manual is to document the Laboratory Operations and Quality Assurance (QA) Program employed by TRACE.

A well-defined system of quality control practices is an important part of providing quality data for our clients. The data produced by TRACE are well defined and defensible.

This manual, with the practices and policies contained in it, are not to be viewed as all-inclusive. Rather, they are to be used as a foundation by TRACE to build upon. The underlying principal for quality assurance is one of continued process improvement of laboratory operations.

The management of TRACE is committed to the continual improvement of its Laboratory Operations and QA Program. While it is the responsibility of the management to put these programs and policies into effect, it is also the responsibility of the entire TRACE team to follow these programs and policies and to make suggestions for the improvement of these programs.

This manual is intended to assist our clients with basic information of laboratory operations. It is also intended to be a resource for our clients so that their projects requiring analytical services will be built upon a strong foundation of quality.

Safety:

Safety is a primary focus at TRACE.

Safety takes precedence over all other laboratory operations.

The management at TRACE provides a safe working environment for its staff. TRACE staff includes individuals who are trained as Hazardous Materials Specialists. In addition, several staff members have first aid training to assist with health and safety issues.

A health and safety session is a required part of new employee orientation. As part of their training, employees are introduced to the specialized health and safety procedures in our Standard Operating Procedures (SOPs). As part of the OSHA 'Worker-Right-To-Know' Act, TRACE maintains an inventory of the chemicals, reagents, acids and solvents used in the course of its operations. Maintained with this inventory are the Material Safety Data Sheets (MSDS) for these materials. These references are available for use by the staff. Should a client have need for information on a particular material, TRACE can provide the information upon request. TRACE also maintains a library of reference materials to assist with this part of the health and safety program.

TRACE provides safety devices such as protective gloves, laboratory coats, eye protection and first aid stations for its staff.

Each individual must also be responsible for his or her health and safety. They must also be aware of others who may be impacted by their actions. If they are unsure about the potential hazard to themselves and/or others, they must ask their Area Manager for assistance.

TRACE will work with our clients to ensure that the laboratory will do what is practicable to assure the safety of materials sent by the laboratory to its clients. Further, TRACE will seek to determine if a client's project poses a health and safety risk and will work with that client to minimize that risk.

Specific safety issues for the laboratory are addressed in general terms in this manual by laboratory area and in the laboratory safety manual. Analytical and field sampling SOPs also have more specific information on safety concerns for specific procedures.

Data Integrity:

Data integrity is a primary focus at TRACE.

Integrity is defined as 'the state of being unimpaired' as well as 'the adherence to moral and ethical principles'.

Data integrity depends on the ability to define and defend the entire analytical process and to prove that the data has been 'unimpaired' and analysis has been performed in accordance with the appropriate procedures and practices.

The ability to define and defend the entire analytical process and the integrity of the data that are produced is dependent upon the documentation of activities and actions. This manual will explain the documentation procedures employed by TRACE in order to produce data that is 'unimpaired.'

This documentation starts with project initiation by the client, project activities by the client and TRACE, and post project activities by TRACE.

All TRACE laboratory employees undergo data integrity training during initial orientation and on an annual basis and must sign that they have attended and understand TRACE's Data Integrity Policy. This training places an emphasis on proper documentation. TRACE's management reviews the data integrity policy annually and it is revised as necessary. It is important for all TRACE employees to understand that while TRACE's goal is to provide the highest quality of data, there are instances where data may be partially deficient and still useful to the client. Employee concerns regarding data integrity may be brought to the attention of either the Laboratory Manager or the QA/QC Manager in confidence. All investigations of data integrity issues will be kept confidential until they are completed and fully documented. The Laboratory Manager monitors data integrity as part of routine data review. Management will document and notify clients immediately if any issues arise that may have impacted client data.

This manual is designed to assist both our clients and TRACE personnel in the production of high quality data, which is usable and defensible.

Ethics:

It is the policy of Trace to provide accurate and reliable data in accordance with client and regulatory requirements. It is against Trace policy to improperly manipulate or falsify data or to engage in any other unethical conduct.

Any employee who knowingly manipulates and/or falsifies data or documents, or engages in any unethical conduct is subject to immediate release from employment.

Employees will be informed of their data integrity and ethics responsibilities at the time of hire and annually thereafter. Employees will be required to sign an Ethics and Data Integrity Agreement stating that they understand the Ethics and Data Integrity Policy and their responsibilities as a TRACE employee.

SECTION 2: Quality Policy Statement and Objectives

Quality Policy Statement:

TRACE is a full service, independent, commercial testing laboratory that is accredited in accordance with the National Environmental Laboratory Accreditation Program (NELAP), the Department of Defense Environmental Laboratory Accreditation Program (DoD-ELAP), and ISO/IEC 17025:2005. TRACE provides analytical services to residential, industrial, engineering, and consulting clients, as well as local, state, and federal agencies, including the Department of Defense. Trace is a Contract Laboratory for the Michigan Department of Natural Resources and Environment, and is Drinking Water Certified by the State of Michigan.

TRACE was established in 1989 to specialize in environmental testing, particularly the analysis of water, wastewater, soil, drinking water, air, and hazardous waste. TRACE management is committed to good professional practice and continual improvement while providing quality analytical testing to its clients.

Any sample collected by, or submitted to, Trace for analysis may have significant implications to the environment or the health and safety of individuals. The importance of this information is such that it may be considered as court evidence or as the basis for conducting environmental remediation.

Therefore, it is the objective of Trace to follow a strict QA Program to maintain the reliability and defensibility of all generated data. TRACE management is committed to ensuring compliance with the standards set forth by their accrediting bodies, including TNI (The NELAC Institute) Standard and The DoD Quality Systems Manual for Environmental Laboratories. This document is provided to serve as a framework for fulfilling that objective.

TRACE recognizes that a good QA Program is not static but must be revised as new ideas and procedures become available. Above all, this document must serve as a reference to our employees to describe quality procedures and practices that must be followed during day-to-day operations. Management continually works to ensure that all personnel understand the importance of their work and how it contributes overall to the quality objectives set forth by management.

This QA Manual is made available upon request. However, to maintain the dynamic nature of the QA Program at TRACE, portions of this manual may change without client notification.

Quality Objectives:

- Obtain and maintain certifications and accreditations to demonstrate laboratory competence and allow tests covered by these programs to be performed.
- Maintain an organization of qualified and trained personnel who are knowledgeable in and follow the procedures and policies stated in the QA Program.

- Maintain adequate facilities (site and instrumentation) to allow personnel to perform accurate and valid chemical tests in a safe environment, and take appropriate precautions when tests are performed at sites other than the permanent laboratory.
- Ensure that personnel are not influenced or pressured by internal or external entities to the point that it may affect the quality of their work.
- Obtain, maintain, and calibrate equipment and instrumentation required to accurately and efficiently carry out chemical tests as prescribed in test methods.
- Collect and receive samples under strict chain-of-custody procedures and adhere to proper sample collection and preservation techniques.
- Ensure that the client's confidential information and proprietary rights are protected during sample receipt, analysis, reporting, data storage, and sample disposal.
- Ensure that personnel are not involved in conflicts of interest or other activities that may diminish client confidence in our competence, impartiality, judgment or integrity.
- Purchase, use, or prepare appropriate reagents and standards. When possible these will be ACS grade, spectroquality, or traceable to NIST standards.
- Use, adapt, or develop "rugged" analytical methods. Whenever available, EPA, ASTM, AOAC, NIOSH, Standard Methods or other recognized and accepted methods will be used.
- Establish levels for quality of laboratory data (accuracy and precision) whenever these are not specified by the analytical methods or a regulatory body.
- Maintain clear, complete and accurate records of all laboratory data and issue accurate reports thereof to clients.
- Perform quality control checks on instruments, methods and analysts to rapidly detect errors and prevent recurrence of errors. This will be accomplished through use of standards, blanks, replicated and spiked samples to check accuracy, precision, and matrix effects.
- Corrective actions will be taken and documented whenever a process is outside of the specified control limits.
- Monitor competence of personnel and adequacy of the Quality Control (QC) Program through intra-laboratory and inter-laboratory efforts.
- Maintain a complete, up-to-date QA Manual that describes the QA Program in sufficient detail to ensure that all personnel have a clear understanding of their responsibilities within the QA Program.
- Make the QA Manual available and adhered to by all employees. The manual will be available to laboratory auditors and clients upon request.
- Ensure that laboratory practices are in agreement with the contents of the QA Program as stated in the manual.

- Audit the QA Program periodically to assure compliance. Audits will consist of system audits, data audits, and performance evaluation samples.

- When work is subcontracted to other laboratories, be responsible to the client for the subcontractor's work. Subcontract laboratories used for Department of Defense work must have an established and documented laboratory quality system that complies with DoD ELAP requirements, and must get project-specific approval by the specific DoD Component before any samples are analyzed.

SECTION 3: Organization and Responsibilities of Quality Control Staff

Statement of Purpose:

It is the policy of management that the assurance of analytical quality is the responsibility of all TRACE employees. TRACE Management is committed to good professional practice and the quality of testing performed for our customers. We believe that the production of accurate analytical data is the most important service we can offer to our clients. To that end, the following job descriptions and associated responsibilities are included in the TRACE QA Program.

President:

The President is responsible for the overall management of the company. The duties of the President encompass tasks necessary to ensure production control, financial management, product quality, sales and marketing success, and administrative support functions. The President shall have overall authority in the management of the QA Program and will make sure that all aspects of the program comply with current and appropriate regulatory requirements, methodologies, and protocols. The President will have absolute authority to make any additions, deletions, or changes to the program as deemed necessary.

Senior Vice President:

The Senior Vice President is responsible for the overall management of the company in conjunction with the President. Ultimate decisions about financial and personnel matters are a primary function. In addition, the Senior Vice President is available to the staff as a technical advisor and chemical consultant.

Laboratory Manager:

The Laboratory Manager shall oversee all aspects of laboratory operations. The Laboratory Manager shall work with the QA/QC Manager to insure that analysts and technicians follow current and appropriate regulatory requirements, methodologies, protocols, and compliance with the TNI Standard and the DoD QSM.

If the Laboratory Manager is absent for a period of time exceeding 15 consecutive calendar days he/she shall designate another full-time staff member meeting the qualifications of the Laboratory Manager to temporarily perform this function. If this absence exceeds 35 consecutive calendar days, the primary TNI accrediting authority must be notified in writing. If this absence exceeds 65 consecutive calendar days, the DoD-ELAP accrediting authority must be notified in writing. TRACE requires that the Laboratory Manager possess a Bachelor's degree and recommends that they have relevant laboratory experience.

QA/QC Manager:

The QA/QC Manager will make sure that all aspects of the program comply with current and appropriate regulatory requirements, methodologies, and protocols. The QA/QC Manager will coordinate and manage the QA Program on a daily basis. The QA/QC Manager must have functions independent from laboratory operations for which he/she has QA/QC oversight and must be able to evaluate the data objectively and perform assessments without outside influence. He/she shall ensure compliance with the TNI standard and the DoD QSM. The QA/QC Manager shall keep members of the quality assurance group informed on issues relating to the laboratory QA Program. The QA/QC Manager reports to the company President.

Laboratory management must appoint a deputy QA/QC Manager in the absence of the QA/QC Manager, to perform this function. TRACE requires that the QA/QC Manager possess a Bachelor's degree, must have a general knowledge of the methods for which any data review is performed, and recommends that they have relevant experience.

Laboratory Area Managers, Analysts, and Technicians:

All analysts and technicians are responsible to prepare and analyze the required quality control samples. Upon completion of each test, the laboratory area managers will compare results to the quality control limits that have been established for that test. TRACE recommends that all technicians possess a high school diploma and that analysts have completed at least 2 years of higher education.

Laboratory Area Managers, Laboratory Manager, and QA/QC Manager will ensure that all analytical and operational activities of the laboratory are properly documented.

Laboratory Area Managers and the Laboratory Manager are responsible for the supervision of the personnel in their respective departments and documentation of the quality of all data reported from their respective departments.

If a Laboratory Area Manager is absent for a period of time exceeding 15 consecutive calendar days he/she shall designate another full-time staff member meeting the qualifications of the Laboratory Area Manager to temporarily perform this function. If this absence exceeds 35 consecutive calendar days, the primary TNI accrediting authority must be notified in writing. If this absence exceeds 65 consecutive calendar days, the DoD-ELAP accrediting authority must be notified in writing. TRACE recommends that any Laboratory Area Manager possess a Bachelor's degree and requires that they are experienced in the fields of accreditation.

Sample Receiving Personnel:

Sample Receiving Personnel will assure that all samples are logged into the laboratory accurately and completely and will ensure that samples received at TRACE represent those indicated on the accompanying chain-of-custody. They will check all sample paperwork for accuracy, obtain required signatures, complete the log-in checklist, and make sure that samples and required analytical tests are properly identified. TRACE recommends that sample receiving personnel possess a high school diploma or equivalent.

Project Managers:

Project Managers will double-check all sample paperwork for accuracy, required signatures, and completed log-in checklist(s), and will make sure that samples and required analytical tests are properly identified. The Project Managers are responsible for accurately obtaining this information, entering it into the Laboratory Information Management System (LIMS), and communicating client needs to the laboratory.

Project Managers are responsible for promptly notifying clients, in writing, of any event that jeopardizes the integrity of data in any report, and documenting this in the project file. TRACE recommends that Project Managers possess a Bachelor's degree.

SECTION 4: Quotation Review and Contract Review

Quotation Review:

Requests for quotation may be sent to the following address:

Request for Quotation
c/o Trace Analytical Laboratories, Inc.
2241 Black Creek Road
Muskegon, MI 49444-2673

Each request for quotation received by TRACE will be reviewed by one of, or a combination of the following:

- Sales Team
- Project Manager
- Laboratory Manager

The review will determine if the project is within the capabilities of TRACE and ensure that all requested requirements can be met. After reviewing the request for quotation, a written response for the requested quotation will be provided.

Contract Review:

Contracts for review should be sent to the attention of the SalesTeam, Project Manager, or QA/QC Manager.

Each contract received by TRACE will be reviewed by the appropriate team of individuals. This review will be conducted to determine whether or not the contract differs from the original project quotation. Such a review will also be made to determine if the project is within the capabilities of TRACE and to ensure that all contractual requirements can be met. After reviewing the contract, any requirements differing from the original project quotation will be noted and discussed verbally or in writing with the client. Any changes to a contract will undergo the same review process as the original contract and the client will be notified.

Subcontract laboratories used for Department of Defense Environmental Restoration work must be DoD ELAP accredited, and must get project-specific approval by the specific DoD Component before any samples are analyzed.

Subcontract laboratories used for NELAP work must be NELAP accredited and comply with the TNI Standard, and must get project-specific approval by the client before any samples are analyzed.

A register of our subcontractors is currently maintained by our Invoicing Specialist. Prior to any NELAP or DoD work, a review of any subcontractors certifications will be performed.

SECTION 5: Document Control, Record Keeping, and Computers and Electronic Data Related Requirements

Data generated by TRACE could potentially be legal evidence. Therefore, it is imperative that integrity and confidentiality are maintained, including all records pertaining to national security concerns. All records will be permanent, complete and retrievable. To this end, all records will be written in ink. All changes will be accomplished by drawing a single line through the error, initialing, dating, and writing the correct information nearby. All records are maintained for a minimum of 7 years and can be retrieved by TRACE staff if the Project Manager is notified within that timeframe. In the event that the company transfers ownership or closes, all clients will be notified for further instructions on the maintenance of their records. All records will be retained for 7 years and in cooperation with the appropriate regulatory and state legal requirements. If any documents are to be retained for knowledge or legal purposes, they are to be noted as such. Documents, logs, and records include the items listed in this section:

Quality Assurance Manual:

The QA/QC Manager is responsible for the preparation, maintenance, and updating of the QA Manual. The master copy of the QA Manual is maintained in the QA/QC Manager's office. Any changes will require the signatures of the Laboratory Manager, QA/QC Manager, President, and Senior Vice President. Changes in the QA Manual due to changes in the company's practices and procedures will be made to ensure that the contents of the QA Manual accurately reflect laboratory operations. The updated text will be noted in blue. Because the QA Manual is considered a controlled document, one hard copy is stored in the QA/QC Manager's office, and the only other controlled copy is a pdf file which is available to all analysts on the company network.

Standard Operating Procedures:

Standard Operating Procedures (SOPs) are required for all analytical procedures, log-in and custody procedures, and corrective action protocols. Although detailed analytical methods are available from the EPA, ASTM, Standard Methods, and other sources, each laboratory is responsible for developing, writing and implementing its own procedures.

Each SOP is given a unique number, which is specific to an area of laboratory operations. SOPs are reviewed and updated on an annual basis. The updated text in each SOP is noted in blue. Because SOPs are considered a controlled document, one hard copy is stored in the QA/QC Manager's office, and the only other controlled copy is a pdf file which is available to all analysts on the company network. The employees utilizing the SOPs are required to sign off that they have read and understand the most current version of each SOP they use. Obsolete copies of SOPs are retained, but are removed from all points of use and are watermarked as "obsolete".

SOPs are approved by the Laboratory Manager and QA/QC Manager.

Reports of Analysis:

Reports of analysis are generated electronically through our LIMS software as PDF documents that cannot be altered. Hard copies are not generated unless required by the client. All verbal results are considered preliminary and do not necessarily reflect appropriate review. If a change needs to be made to a client report after it has been issued, an amended version will be created and sent to the client. The amended report will be indicated as such with the reason for the amendment within the cover page of the report.

Reports are confidential client information. The content of reports and other client data will not be divulged except upon request of the client, subpoena, or during state certification inspections which make certain data reviewable under statute (*e.g.*, drinking water data).

If it becomes necessary to remove reports of analysis from the premises for legal proceedings, duplicates will be prepared and placed in the files pending return of the original documents for those clients requiring hard-copy reports.

Electronic reports are kept for a minimum of seven years and then destroyed except for specific client requests, government consent orders, or other legal requirements of record retention.

Laboratory Logbooks:

Laboratory logbooks are kept in the individual laboratories. A separate logbook is used for each type of analysis. Each logbook contains the date of analysis, analyst's initials, batch ID, observations, and may also contain raw data, and calculations for that analysis. Completed logbooks are stored in the QA/QC Manager's Office. Laboratory logbooks are to be kept for a minimum of seven years after completion. Logbooks, which are no longer referred to by the laboratory are removed to a locked storage location off site. Unused portions of logbooks are marked out with a line, dated, and initialed.

Laboratory Data Worksheets:

Benchsheets are used to summarize data for word processing and to record data and data qualifiers from tests that do not supply hard copy or electronic output. Worksheets may also have places for calculations, formulae, etc. All observations will be recorded in laboratory notebooks or worksheets. Completed worksheets are to be forwarded to the Laboratory Area Manager for report assembly and are stored with the reports of analysis. Retention policies are the same as for the reports of analysis.

Equipment Logbooks:

Equipment logbooks are kept to record instrument condition and maintenance experience. Logbooks will be kept by the instrument or in a nearby drawer or cabinet. These records will be kept for a minimum of seven years after the last entry or after disposal of the equipment.

Chain-of-Custody Documents:

Chain-of-custody (C-O-C) documents are used to record the source and transfer of samples between the client and TRACE. The completed C-O-C forms are retained with the copy of the report of analysis. Retention policies are the same as for the reports of analysis.

Hard-Copy Instrument Output:

Instrument output for the organics laboratory such as quantitation reports, spectra, and chromatograms are marked with the sample identity and forwarded with the analytical benchsheets for storage with the retained copy of the reports of analysis. Hard-copy output such as instrument calibration, instrument tuning, blank data, and batch quality control data is retained and filed by the analyst. Instrument output for the metals laboratory consists of multiple samples and clients per page. For this reason, output is retained and filed by the analyst. The instrument hard-copy output for the inorganic laboratory is forwarded with the analytical benchsheets when appropriate, while other output must be retained and filed by the analyst. Retention policies for instrument output are the same as for the reports of analysis.

Client Correspondence:

All client correspondence related to a specific job is recorded on the client correspondence log on the front of each file folder. Any facsimile or e-mail correspondence to a client is to be retained with the related project. Retention policies are the same as for the reports of analysis.

Sample Run Logbooks:

Sample run logbooks are utilized when all the pertinent information cannot be captured on hard-copy instrument output. In these cases, the information must be recorded in a controlled logbook and every sample, standard and quality control check that is analyzed in a sequence is entered into a sample run logbook to document the date of analysis, the analyst's name, batch information, dilutions made, and other pertinent information. Each laboratory has sample run logbooks designed specifically for the analytical method being used. For example, the GC/MS logbook for volatiles includes calibration and instrument tuning requirements as well as a column to enter analytical run times. Several inorganic logbooks include sections that show both the preparative and analytical steps.

The information from the sample run logbooks can be used to check compliance with analytical protocols and as a diagnostic tool for troubleshooting analytical problems. For example, checking the sample run log can be done to ensure that the compounds identified in a sample are not the result of contamination from a previous run.

Sample run logbooks are comb-bound with pages sequentially numbered. When a sample run logbook is completed it is given to the QA/QC Manager for storage.

Retention policies for these logbooks are the same as for the reports of analysis.

Standards:

Every standard, whether prepared for calibration or spiking, is either entered into a standards logbook or into LIMS. These contain all necessary information about the standard including stock standard number, concentration, date prepared, vendor and lot number, purity, expiration date, and storage area. The organic laboratory uses the following format for the standards logbook. The front side of each page contains all relevant information about the stock standards, while the backside contains information about the working standards.

Every stock standard made, whether it is a single compound or a mixture of compounds and/or stock standards, gets a new stock standard number. A new number is required every time a stock is made or combined, even when making up the same stock standard again, with the exception of those made daily where the lot number has not changed. The identification numbers are assigned in one of two ways. The first is alphanumeric, beginning with a prefix that describes the lab area and type of standard, followed by the logbook number and page number where the stock standard preparation information can be found, and ending in zero (when dilutions of the stock standard are made, the zero changes to 1, 2, 3, etc, as appropriate). Additional instructions are found on the inside of each logbook, where applicable. The other option is to have LIMS assign a unique number based on the year, month, and day, followed by a sequential number

Standards logbooks are comb-bound with pages sequentially numbered. Retention policies for these logbooks are the same as for the reports of analysis.

Data Validation Checklists:

Data validation checklists are provided for those clients who require them. Data validation checklists consist of two parts: Analyst Review and Manager Review. Upon completion of their analyses, the analyst will fill out the appropriate Analyst Review checklist, making sure to sign and date it.

The checklist is method specific but typically includes items such as verification that method blank QC criteria have been met; all quantitation is within the calibration curve or linear dynamic range limit; the Initial Calibration Verification (ICV) and Continuing Calibration Verifications (CCVs) have passed QC criteria; Laboratory Control Sample (LCS) data have been checked against QC criteria; and samples have been analyzed within holding time.

The Laboratory Area Manager will fill out a Manager Review checklist after an Analyst Review has been completed. The analytical method or specific analysis will be filled out at the top of the form and the checklist is signed and dated at the bottom. The Manager Review includes items such as verification that analyst initials are on the benchsheet; analysis in the file matches request on the C-O-C; qualitative and quantitative results have been checked; transcriptions are correct; quality control issues are explained on the benchsheet; and so on.

The data validation checklists are kept with the reports of analysis.

QA/QC Data:

The raw quality control data, which validates the sample results, are retained by the laboratory in a manner allowing for easy retrieval. The method of storage depends on the nature of the raw data. Some instruments integrate calibration data, QA/QC data and sample data together on a page so that separating one from another would require dividing the page itself. In this case, all the data, (QA/QC included) is filed by the analyst according to the method and the date of analysis. Other instruments give each standard or sample a printout of its own so that there are no shared pages. In this case, the QA/QC data that are associated with particular samples (*e.g.*, surrogate data from chromatograms or Matrix Spike/Matrix Spike Duplicate-MS/MSD data) are maintained in the client's project file from which the particular samples come. The other QA/QC data, which are associated with a complete batch or run of samples and not with any one sample in particular (*e.g.*, laboratory control sample data or calibration verification data) are filed by the analyst by date analyzed.

Program Compliance Records:

All records related to compliance with the State of Michigan, Department of Defense, National Environmental Laboratory Accreditation Program, or any other agency or organization will be made available to certifying, validating, or accrediting authorities.

Computers and Electronic Data Related Requirements:

The Laboratory Information Management System (LIMS) is manufactured by Promium, and the software program is titled Element. The LIMS is on the company network, which is password protected. In addition, access to the LIMS itself is password protected. Only authorized users can access the LIMS. The LIMS is able to monitor log-on failures and break-in attempts. System operating privileges are controlled by the LIMS administrator.

As the laboratory receives samples, they are entered into the LIMS and provided with a barcode label. The samples are then scanned, initiating an internal chain-of-custody, and released to the designated storage area or directly to an analyst. The analyst retrieves a sample from storage and scans it into his/her custody. The analysis is performed and the sample is scanned back to storage or to disposal.

The analyst builds an analytical batch, analyzes the samples and then posts the results with the associated quality control (as controlled by the batch rule) into LIMS. The Laboratory Area Manager then reviews the data before being released for reporting.

The LIMS automatically uses the user's name and password to identify any entries made by that person. The system is equipped with an audit trail function, which tracks changes to a database. The audit trail function records:

- The original data and the modified data
- The identity of the person who made the change
- The dates of the original and modified data

The LIMS database and all electronic data on the company network are continuously backed up to prevent the loss of data on a separate server that is co-located with an off-site service. All electronic data/instrument data not located on the company network, is backed up once a month. This back up is stored on site in a fire resistant storage cabinet.

Instructions for the proper use of the LIMS are provided by Promium, and can be accessed through LIMS. To access instructions, an employee must first gain access to the company network using their network user name and password, and then gain access to the LIMS using their LIMS user name and password, which are assigned by the system administrator. Each user belongs to a 'user class' which allows/restricts their privileges within the LIMS. Examples are the ability to make changes to data once it has been saved and the ability to schedule work.

Once access to LIMS has been attained, the "Help" category is selected from the top drop down menus. This provides the user seven choices for help windows:

- Help Topics

- New User Tutorial
- Data Tool Tutorial
- Promium (Internet)
- SW-846 Methods (Internet)
- About Element
- Revision History

Help Topics:

Help Topics provides instructions on the LIMS in the following categories:

- Introduction
- Quick Start
- File/Login
- Print
- Sample Control
- Laboratory
- Project Management
- QA Admin
- Database Admin
- Help
- Index

Specific instructions in the above categories can be accessed by:

- Clicking on the Chapter in the Contents drop-down
- Clicking on the specific topic in the Index drop-down
- Using the Search drop-down

New User Tutorial:

The New User Tutorial is a pdf version of the Element DataSystem Tutorial. This is a step-by-step introduction to Element, and is an excellent resource for the first time user.

DataTool™ Tutorial:

DataTool™ allows electronic data entry form the analytical instrument to the Element DataSystem™ database. DataTool™ Tutorial takes the user step-by-step through the data transfer operation.

Promium (Internet):

The Promium (Internet) is a link to the Promium Web site.

SW-846 Methods (Internet):

The SW-846 Methods (Internet) is a link to the Environmental Protection Agency SW-846 Analytical Methods.

About Element:

About Element provides software system information.

Revision History:

Revision History provides revision information on the current and previous revisions.

SECTION 6: Control of Supplies

In order to ensure that purchased supplies, reagents, and consumables comply with method specifications or requirements, these materials are specified for purchase by an analyst responsible for knowing the method requirements. When the items are received, the purchasing agent checks the packing slip against the items received, and against the order to ensure what was received is what was ordered. The purchasing agent then signs and dates the packing slip.

Reagent Grade Chemical, Acids and Reagents:

Chemical reagents, solvents, gases, etc. are available in many grades of purity. In order to produce high quality, reproducible data, it is necessary to obtain materials of the appropriate quality required for the analyses to be performed. It is also important to ensure that the quality of reagents used for specific procedures is consistent over time.

It is the policy of TRACE to use only reagent grade, ACS grade, or better quality materials for the preparation of analytical standards and reagents. Where necessary, TRACE will order and utilize chemicals, acids, and reagents that have been assayed for purity.

Labels on all material will be inspected upon receipt to determine whether the reagent quality meets the specifications for the analytical method and to determine whether the material has adequate shelf life.

High Purity Solvents:

Solvents used for gas chromatography, high performance liquid chromatography and mass spectrometry are of the highest purity available, HPLC or Pesticide Residue grade. It is also the policy of TRACE to frequently run a solvent blank during an analysis sequence. The use of such blanks is beneficial to detect the presence of trace impurities, which may have been introduced from the solvents. Solvent blanks are normally run once a day, or more often as interference or suspect samples dictate.

Purchased Analytical Standards:

It is often beneficial to purchase analytical reference standards at prepared concentrations. TRACE purchases such standards for atomic absorption, ICP spectroscopy, HPLC, gas chromatography, wet chemistry, and mass spectrometry. Records are maintained which document the composition and purity of purchased standards. The following sources have been found to provide analytical standards of acceptable quality.

Metals Analysis: Atomic Absorption and ICP and ICP-MS Standards:

Standards are purchased from Fisher, Accustandard, Inorganic Ventures, SPEX Industries, Inc. and other suppliers.

HPLC, Gas Chromatography and Mass Spectroscopy Standards:

Standards are purchased from Supelco Chromatography Supplies, Accustandard, NSI, or Absolute Standards.

Wet Chemistry:

Standards are purchased from Fisher, Accustandard, or Hach Chemicals.

Microbiological Analysis:

Media purchased from vendors will be of a quality that is acceptable under the guidelines of the EPA approved drinking water certification program administered by the State of Michigan. Dilution water is DI water that is nutrient enriched and sterilized at 15 psi for 30 minutes.

Storage of Reagents:

Reagents, standards and solvents will always be stored in accordance with manufacturer's instructions. Incompatible materials, *e.g.*, organics and peroxides or perchlorates, will not be stored together. Acids and bases will be stored in appropriate cabinets. Flammable materials will be stored in flammable solvent storage cabinets.

Deionized Water:

The reagent used in the largest quantity in the laboratory is deionized water. Deionized water at TRACE is used by all of the laboratories and the field-sampling department. The water is prepared using deionization following reverse osmosis. The ion exchange tanks are supplied by Kohley's Eco-Water Systems and are located in the back storage area.

Deionized water is tested monthly for conductivity, heterotrophic plate count, and residual chlorine. The deionized water is continually monitored for resistivity and the deionization cartridges are changed when the conductivity is > 0.056 μmho/cm. Deionized water is checked annually for bacteriological suitability and for Lead, Cadmium, Chromium, Copper, Nickel, and Zinc.

SECTION 7: Equipment Calibration and Maintenance

Equipment Calibration and Maintenance:

To provide high quality data, it is essential that all laboratory and field equipment be in satisfactory operating condition. (For a list of major equipment, see Appendix IV) To this end, TRACE performs routine equipment calibration and maintenance. This includes the following:

Gas Chromatographs:

Analysis done by gas chromatography will follow SW-846 protocols except in those cases where 40 CFR Part 136 methods or drinking water methods are warranted. The instrument will be calibrated using a minimum of a five-point calibration curves for all analytes. Continuing calibrations utilizing a midpoint standard are performed after every ten samples to check the validity of the multi-point curve. The value of the continuing calibration standard must agree within plus or minus 15% of the initial value or appropriate corrective action is taken, which may include recalibrating the instrument. The calibration standards are commercially available certified standards and are spiked with internal standards. All standard solutions are traceable to NIST or other reliable standards and certificates of analysis for these standards are maintained. Reference standards are used for no other purpose other than instrument calibration and calibration verification.

Gas Chromatographs/Mass Spectrometers:

Prior to calibration, the instruments used for gas chromatography/mass spectrometry (GC/MS) analyses are hardware tuned by analysis of p-bromofluorobenzene (BFB) for volatile analyses and decafluorotriphenyl phosphine (DFTPP) for semi-volatile analyses. The instrument tune will be verified every twelve hours of operation.

Once the tuning criteria for these reference compounds are met, the instrument is initially calibrated using a minimum of a five-point calibration curve. Continuing calibration is verified as specified in the method being used. Under SW-846 protocols, the Continuing Calibration Compounds (CCCs) and System Performance Check Compounds (SPCCs) are checked every twelve hours. Under 40 CFR Part 136 protocols, the continuing calibration is checked daily. The calibration standards are commercially available certified standards and are spiked with internal standards.
All standard solutions are traceable to NIST or other reliable standards and certificates of analysis for these standards are maintained. Reference standards are used for no other purpose other than instrument calibration and calibration verification.

Analytical Balances:

The analytical balances are checked for proper leveling at the beginning of each day. The accuracy of the calibration is then checked with a 100-milligram, one 1-gram, a 10-gram and a 100-gram class "S" weight. The class "S" weights must weigh ±0.0002g. All calibrations are recorded in the balance calibration logbook.

The calibration weights are compared annually to reference mass standards that are directly traceable to the NIST. The calibration weights are used for no other purpose other than to verify the calibration of the balances.

Top Loading Balances:

The top loading balances are checked for proper leveling at the beginning of each day. The accuracy of the calibration is then checked with a ten (10) gram and either a two hundred (200) gram or five hundred (500) gram class "S" weight. The class "S" weights must weigh ± 0.02g. All calibrations are recorded in the balance calibration logbook.

The calibration weights are compared annually to reference mass standards that are directly traceable to the NIST. The calibration weights are used for no other purpose other than to verify the calibration of the balances.

The balances are also maintained and calibrated annually by an outside firm. Calibration labels are placed on each balance during the annual inspection.

pH Meter Calibration:

The pH meters are calibrated against two (2) reference standards prior to each use. A third reference standard is analyzed to verify the accuracy of the calibration. All calibrations are recorded in the pH logbook.

Incubators:

The temperatures of the laboratory incubators are checked twice daily. Bacteriological incubators are maintained at 35 ± 0.5 °C and BOD incubators are maintained at 20 ± 1.0 °C. All temperatures are recorded in the incubator temperature logbook.

Refrigeration Units:

The temperature of each walk-in cooler, refrigerator and freezer is checked at the beginning of each day. The coolers and refrigerators are maintained at 0 to 6 °C, freezers are maintained at -10 to -20 °C. All temperatures are recorded in the refrigerator/freezer temperature logbooks.

Atomic Absorption Spectrophotometers:

TRACE employs an Atomic Absorption (AA) spectrophotometer using cold vapor (for mercury analysis) and an Atomic Fluorescence Spectrometer (for low-level mercury). These are calibrated daily with a blank and at least the number of standards required by the protocol of the method being applied. First-order regression is used to generate a calibration equation, which computes analyte concentration as a function of absorbance. Initial and continuing calibration checks are analyzed to verify the validity of the curve.

The instrument operator responds to the failure of a calibration check by investigating and addressing any problem as necessary and recalibrating, thus assuring that all data is generated with a valid calibration curve.

All standard solutions are traceable to NIST or other reliable standards and certificates of analysis for these standards are maintained.

Inductively Coupled Plasma (ICP) Atomic Emission Spectrophotometers:

The ICP atomic emission spectrophotometer is calibrated daily with a blank and standard, unless client protocols call for a different procedure (*i.e.* the USACE requires the use of a blank and three standards.) One concentration is measured as a function of the intensity of light emitted by the element of interest at whatever discreet wavelength is being monitored. The calibration is verified by initial and continuing calibration checks and spectral interference checks. The instrument operator responds to the failure of a calibration check by investigating and addressing any problem as necessary and recalibrating, thus assuring that all data is generated with a valid calibration curve. The failure of a spectral interference check is remedied by monitoring a different wavelength free from interference or by adjusting background correction points.

All standard solutions are traceable to NIST or other reliable standards and certificates of analysis for these standards are maintained.

Inductively Coupled Plasma Mass Spectrometer (ICP-MS):

Calibration of the ICP-MS consists of a calibration curve that has one blank and three calibration standards. Calibration is done on a daily basis for each element that is to be analyzed. Additionally, during the analysis of environmental samples an Initial Calibration Verification (ICV) and an Initial Calibration Blank (ICB) are run to verify calibration of the instrument. A Continuing Calibration Verification (CCV) is also run after every 10 samples along with a Continuing Calibration Blank (CCB).

A Linear Dynamic Range (LDR) is determined at least once a year or more often if the analyst believes that the response of the instrument has changed due to a change in instrument hardware or in instrument operating conditions. The LDR is determined by calibrating the instrument for the analyte of interest, and then analyzing successively higher standards in excess of the calibration standard concentration. The highest standard that can be analyzed which also has a recovery of 90% or greater is defined as the LDR limit. Sample concentrations that exceed 90% of the LDR limit must be diluted and reanalyzed.

All standard solutions are traceable to NIST or other reliable standards and certificates of analysis for these standards are maintained.

Lachat QuikChem ® 8500:

The Lachat QuikChem® 8500 is calibrated with a blank and five to nine standards, depending on the analyte that is being analyzed. A standard curve is prepared by plotting instrument response against the concentration values. Continuing calibration is checked by running a mid-range standard every ten samples.

All standard solutions are traceable to NIST or other reliable standards and certificates of analysis for these standards are maintained.

Konelab Aqua 20:

The Konelab Aqua 20 is calibrated with a blank and 5 or 6 standards, depending on the analyte to be analyzed. A standard curve is prepared by plotting instrument response against the concentration values. Instrument QC is monitored using ICV, CCVs, CCBs, and second source

standards, as appropriate, depending on the method being used. Batch QC is monitored using LCSs and MS/MSDs.

All standard solutions are traceable to NIST or other reliable standards and certificates of analysis for these standards are maintained.

UV/VIS Spectrophotometers:

Calibrations for the Milton Roy Spectronic 21 spectrophotometer and the Spectronic Instruments Spectronic Genesys 5 spectrophotometer in the Wet Chemistry Laboratory are verified annually. This can be done either using cell standards or with potassium dichromate standards.

Laboratory Thermometers:

All laboratory thermometers will be checked for calibration upon initial usage. All liquid-in-glass thermometers are calibrated annually thereafter against the NIST thermometer and digital thermometers are calibrated on a quarterly basis. The calibration check will be recorded in the thermometer logbook and on a calibration label on each thermometer. The Thermometer Calibration Certificate is maintained with the NIST thermometer. The NIST thermometer is used for no other purpose other than to calibrate laboratory thermometers.

Preventative Maintenance and Preventative Action:

As part of the QA/QC program, a routine preventative maintenance program is conducted by TRACE to minimize the occurrence of instrument failure and other system malfunctions. TRACE staff performs preventative maintenance and repairs, or coordinates with a vendor for the repair of all instruments. All laboratory instruments are maintained in accordance with manufacturer's specifications and the requirements of the specific method employed. This maintenance is carried out on a regular basis and is documented in the laboratory equipment logbook for each instrument. Emergency repair or scheduled manufacturer's maintenance is provided by factory or vendor representatives. For many of the instruments, a supply of spare parts is kept on hand to expedite repairs.

Equipment or instrumentation that has been damaged, gives suspect results, or is otherwise considered defective is taken out of service, identified as defective, and when possible removed from the area of use. In addition, the effect that the damage or defect may have had on previous analyses is investigated, as appropriate.

TRACE employs the use of preventative actions as a proactive approach for improvements and prevention of nonconformities. When a potential nonconformity is identified, an action plan is implemented and evaluated for effectiveness. Refer to SOP 10-29.

Glassware:

Volumetric glassware used in the laboratory must be of "Class A" tolerances. Graduated cylinders and pipettes will be checked by the laboratory before being placed into service to make sure their tolerances are within the limits specified by the manufacturer. This check will be conducted by weighing the glassware on an analytical or top loading balance, filling the piece of glassware to the highest calibration mark with deionized water, and then weighing again on the balance. Ten measurements are made, and the precision and accuracy must meet the appropriate agency's requirements.